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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/147,955	03/24/99	MIZUTANI M	001560-350

EXAMINER	
IBRAHIM, M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/147,955	MIZUTANI et al
Examiner	**Group Art Unit**
Medina A. Ibrahim	1638

☒ Responsive to communication(s) filed on *May 24, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-19* is/are pending in the applicat

Of the above, claim(s) *8 and 12-15* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-7, 9-11, and 16-19* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Applicant's submission of the instant application as a 371 is acknowledged, however the first claim does not provide a single special technical feature that is distinguished over the prior art, as evidenced by Teusch et al who teach a gene for the glucosylation in the 5-position of flavonoid from flowers of Matthiola incana R. Br. (see, e.g., page 586, Abstract). Therefore, the instant invention lacks Unity of Invention and restriction is set forth as it applies to U.S. practice.

Claims 1-19 are pending in this application.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, 9-11, and 16-19 , drawn a gene, coding for a protein having flavonoid 5-o-glucosyltransferase activity , in a vector, a host cell including a plant/cell or a progeny transformed with said vector, and a process for producing and recovering said protein.

Group II, claim(s) 8 and 12-15, drawn to a protein.

2. The inventions listed as Groups I -II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I requires a gene, a vector, and transformed host cell , a transformation and recovery processes which are not required by Group II.

The invention of Group II requires a protein of a multitude of sequences which is not required by Group I.

Because inventions I-II are distinct for the reasons given above, and they have acquired a separate status in the art as shown by their different subject matter and fields of search, restriction for examination purposes as indicated is proper.

During a telephone conversation with Donna M. Meuth on August 22, 2000 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-7, 9-11, and 16-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8 and 12-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Objections

The specification is objected as the SEQ ID Nos: of the sequence listing submitted on May 12, 2000 are not correlated with the SEQ ID Nos defined in the body of the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-11, 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for plant 5GT cDNAs from Perilla, Verbena, Torenia and Petunia coding for enzymes having flavonoid 5-transglycosylation activity or their expressions in yeast cells , does not reasonably provide enablement for any gene from any source encoding a protein or a variant having flavonoid 5-O-glucosyltransferase activity in any plant, its progeny or tissue or a cut flower of said plant having identical properties. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant broadly claims any gene from any source coding for a protein having flavonoid 5-O-glucosyltransferase activity including those encoding SEQ ID NO: 7-10 or 12 or variants modified by addition and/or deletions of one or more amino acids, and/or substitution by one or more other amino acids , or variants that has as low as 30%-50% homology to said amino acid sequences. Applicants also claim variants of 5GT gene that hybridize under low stringency

conditions with all or a portion of the nucleotide sequences that codes the amino sequence of SEQ ID NO: 7 through 10 or 12 and encoding a protein with 5-O-glucosyltransferase activity. Applicant has shown the isolated unmodified nucleic acid sequences from Perilla, Verbena, Torenia and Petunia encoding protein with 5GT activity in yeast cells. Applicant has not taught 5GT genes from other sources or variants of SEQ ID NO: 7 through 10 or 12 or their ability to provide a means of manipulating flower color in plants. No guidance has been presented for the isolation or identification of any 5GT protein having amino acid sequence with as low as 30 % homology to SEQ ID NO: 7-10 or 12 or a protein modified by addition and/or deletion of one or more amino acids and/or substitutions that still maintains flavonoid 5- glucosyltransferase activity as claimed in claim 2, or obtention of nucleotide sequences that hybridize to SEQ ID NO: 1-6 under low stringency conditions still encoding a protein with flavonoid 5- glucosyltransferase activity as claimed in claims 3-5. Applicant has not taught any transformed plant/tissue or progeny expressing exemplified or non-exemplified 5GT genes, or cut flower thereof having identical properties as claimed in claims 10-11 and 16-19.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Isolation of DNA sequences with a specific function is highly unpredictable as it requires specific guidance for probe sequences , hybridization and wash conditions. The instant specification does not provide guidance for how to obtain nucleotide sequences encoding a protein having activity that transfers a glycoside to the 5 position of a flavonoid as broadly claimed, and it is not clear if any has been isolated from other plants at the time of Applicant's invention. For example, see Kossmann et al, Progress in Biotechnol. 10, Proc. Int. Conf. 4/23-26, 1995, pages 275-277, who report the unpredictability associated with the cloning of a gene enzyme involved in starch biosynthesis pathways.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to isolate and characterize all 5GT genes from other sources encoding a protein having flavonoid 5-O-glucotransferase activity and functional variants, and to evaluate their ability to modify flower colour in plants. Therefore, the instant invention could not be practiced throughout the broad scope without undue experimentation.

See Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g a DNA sequence) and page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Claims 1-7, 9-11, 16-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are broadly drawn to a multitude of genes with undefined regulatory encoding a multitude of 5GT protein or variants with a multitude of amino acid deletions and/or additions and/or substitutions. In contrast, the specification only provides guidance for the isolated cDNA sequences from Perilla, Verbena, Torenia and Petunia coding for encoding SEQ ID NO:2 .

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the invention as broadly claimed.

See *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-7, 9-11, 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite in the recitation of "a protein modified by addition and/or deletion of one or more amino acids and/or substitutions" as it is unclear where and which amino acids are modified. Dependent claim 16 is included in the rejection.

In claims 2-5 , " amino acid sequence described in any one of SEQ ID Nos: 7 through 10" is vaque . The word "described" should be replaced with --- as shown---. Dependent claims 6-7, 9-11 and 16-19 are included in the rejection.

Claims 10-11 and 16-19 are indefinite in the recitation of "identical properties", which is not defined in the specification, as it is unclear what properties are identical.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is directed to a naturally occurring gene and therefore does not constitute patentable subject matter. See *American wood v. Fiber Distintegrating Co., 90 U.S. 566 (1974), American Fruit Growers v. Brogdex Co., 283 U.S. 2(1931), Funk Brothers*

Seed Co. V. Kalo Inoculant Co., 33 U.S. 127 (1984), Diamond v. Chakrabarty, 206 USPQ 193 (1980).

Amendment of claim 1 to change "A" to --An isolated nucleotide sequence --- would overcome the rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

8.

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by each Teusch et al or Jonsson et al

The claim is directed to a naturally occurring gene coding for a protein having flavonoid 5-O-glucosyltransferase activity.

Each Teusch et al and Jonsson et al teach the naturally ocurring plants which inherently contain the claimed gene (see, e.g; Jonsson et al, page 341, Abstract; Teusch et al, page 586, Abstract).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jonsson et al in view of Sambrook et al (Lab. Manual, 1989).

Claims are drawn to a gene from *Petunia hybrida* coding for a protein, with specified amino acid sequence, having flavonoid 5-O-glucosyltransferase activity.

Jonsson et al teach isolated and purified anthocyanin 5-O-glucosyltransferase from *Petunia hybrida* and suggested the importance of 5GT gene encoded by said protein(see, e.g., pages 344-345).

Jonsson et al do not teach the claimed specific amino acid or their nucleotide sequences.

Sambrooke et al teach methods of cloning , isolating and sequences of genes or cDNAs (see, e.g., whole document).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the method for isolating and purifying flavonoid 5-O-glucosyltransferase protein, and to modify that method by incorporating the molecular cloning techniques taught Sambrooke et al, to produce the 5GT gene or protein , given the importance of 5GT in *Petunia hybrida* as taught by Jonsson et al. Thus, the claimed invention as whole was clearly *prima facie* obvious.

Claims 1-7, 9-11, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brugliera et al (US 5,859,334, filed March 1995) in view of Jonsson et al and Sambrooke et al.

Brugliera et al teach isolated nucleic acid sequences encoding anthocyanidin -3-glucoside rhamnosyltransferase or 3RT from *Petunia hybrida* and methods of their use for the production of pigmentory molecules and transgenic plants with modified colors (see, columns 12, 21, 23-24, Examples 1, 10, and 12-13), and suggest, in column 3, lines 30-35, an isolated nucleotide sequence encoding a plant flavonoid 5-O-glucosyltransferase for similar use .

Brugliera et al do not teach the claimed flavonoid 5-O-glucosyltransferase sequences.

Jonsson and Sambrooke teach isolated and purified anthocyanin 5-O-glucosyltransferase from *Petunia hybrida* and suggested the importance of the gene encoded by said protein.

It would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize the method of isolating and using nucleotide sequences encoding a plant flavonoid glycosylating enzyme as taught by Brugliera , and to modify that method by

incorporating the flavonoid 5-O-glucosyltransferase protein sequences from *Petunia hybrida* taught by the combined teachings of Jonsson and Sambrooke, to produce transgenic plants with modified flower colors or for the production of purified protein as taught by Brugliera et al, given the importance of flavonoid glycosylating enzymes as taught by Brugliera et al. Therefore, the claimed invention as whole was clearly *prima facie* obvious.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The examiner can normally be reached on Monday-Tuesday, and Thursday from 7:30 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

September 7, 2000
mai

PAULA HUTZELL
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